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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,538	07/19/2001	Josephine Egan	14014.0346U1	5705
23859	7590	06/14/2005	EXAMINER	
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,538	EGAN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-10,12,16-21,23,25,27,29,31-34,36,37 and 53-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5-10,12,16-21,25,29,31-33 and 53 is/are allowed.
- 6) ☒ Claim(s) 23, 27, 36, 37 and 54-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/23/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's amendment filed on 28 March 2005 is acknowledged and entered. Following the amendment, claims 2, 3, 13, 14, 26, 30, and 39-52 are canceled, claims 1, 5-9, 12, 16-20, 23, 25, 27, 29, 31-34, 36 and 37 are amended, and the new claims 53-74 are added.

Currently, claims 1, 5-10, 12, 16-21, 23, 25, 27, 29, 31-34, 36, 37 and 53-74 are pending and under consideration.

Inventorship

In view of the paper filed on 10 November 2004, the inventorship in this nonprovisional application has been changed by the addition of Joel Habener and Doris Stoffers.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 2, 3, 13, 14, 26, 30 are moot as the applicant has canceled the claims.

The rejection of claims 1, 5-10, 12, 14, 16-21, 23, 25, 27, 29, 31-34, 36 and 37 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The prior art rejection of claim 31 under 35 U.S.C. 102(b) as being anticipated by Eng, US 5,424,286, is withdrawn in view of applicant's amendment of the addition of the new limitation of "*in vitro*" in line 2, which is *not marked* up.

The prior art rejection of claim 31 under 35 U.S.C. 102(b) as being anticipated by Dupre (WO 95/31214), is withdrawn in view of applicant's amendment and for the same reasons above.

The prior art rejection of claims 23 and 31 under 35 U.S.C. 102(b) as being anticipated by Edvell et al. (Experimental and Clinical Endocrinology & Diabetes, 1997, 105(4): A 36), is withdrawn in view of applicant's amendment and for the same reasons above.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 27, 36 and 37 remain rejected, and the new claims 54-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Eng, US 5,424,286, for the reasons set forth in the previous Office Actions, paper No. 10 and 15, and the ones mailed on 1/13/04 and 9/27/04.

Applicants argument filed on 28 March 2005 has been fully considered, but is not deemed persuasive for reasons below.

At pages 13-15 of the response, the applicant argues that the law requires that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, that claims 23 and 27 are amended to include a method step of “administering by one or more injections ... daily for at least three (claim 23) or at least two days (claims 27 and 36) ...”, and that thus, this method step distinguishes the claimed invention from the ‘286 patent, as the patent does not disclose each and every element of the amend claims, and in fact none of the experiments in the cited art lasted longer than four hours. This argument is not persuasive because although Eng does not explicitly specify administering by one or more injections ... daily for at least two or three days, the reference teaches the use of the insulintropic agents GLP-1 and exendin-4 for the treatment of type I and type II diabetes. It is well established and practiced that diabetes requires one or more daily injections of insulintropic agent for lifetime, which is “at least two or three days”. As such, it is inherently true that Eng’s method of treating diabetes would comprise the step of one or more injections daily for at least two or three days, and that it would have the effect on differentiating non-insulin producing cells into insulin producing cells as that of the present invention since the instant claims, as written, do not distinguish themselves from the prior art in the active ingredient used and *method steps*.

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Claim 23 remains rejected, and the new claims 57, 63 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Dupre (WO 95/31214), for the reasons set forth in the previous Office Actions.

Applicants argument filed on 28 March 2005 has been fully considered, but is not deemed persuasive for reasons below.

At pages 15-16 of the response, the applicant presents the similar argument as that above. This argument is not persuasive for the same reasons above.

Conclusion:

Claims 1, 5-10, 12, 16-21, 25, 29, 31-33 and 53 are allowable, as they are directed to isolated insulin-producing cells that do not originally produce insulin, only do so after in vitro treatment with GLP-1 or Exendin-4, and possess other functional properties. Although such insulin-producing cells produce insulin as β cells do, they are distinct from β cells, in view of the instant disclosure. For example, the specification discloses that AR42J cells, which are acinar cell line, upon the treatment with GLP-1, produce insulin (Figure 27), and meanwhile remain secretion of amylase (Figure 15). However, β cells or insulinoma cells, while produce insulin, do not secrete amylase.

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Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



**LORRAINE SPECTOR
PRIMARY EXAMINER**

Dong Jiang, Ph.D.
Patent Examiner
AU1646
5/31/05